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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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01/27/2006

Ian Alexander Shiels

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EXAMINER

BRADLEY, CHRISTINA

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

03/13/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/531,560	<b>Applicant(s)</b> SHIELDS ET AL.	
	<b>Examiner</b> Christina Marchetti Bradley	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 10-23 is/are pending in the application.
- 4a) Of the above claim(s) 3-5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 10-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1-5 and 10-23 are pending. Claims 3-5 are withdrawn from consideration and claims 21-23 are new.

### ***Claim Objections***

2. Claims 13 and 14 are objected to. For clarity, the phrase "wherein said compounds have chemical structures" should be inserted before "as follows". Alternatively, the claims could be constructed in a manner analogous to claim 21.

### ***Claim Rejections - 35 USC § 112***

3. Applicant's arguments, see pages 39-41, filed 10/16/2007, with respect to 35 U.S.C. 112, second paragraph, have been fully considered and are persuasive in light of the amendments to the claims. The rejection of claim 20 has been withdrawn.

4. Applicant's arguments, see pages 41-46, filed 10/16/2007, with respect to 35 U.S.C. 112, first paragraph, have been fully considered and are persuasive in light of the amendments to the claims. The rejection of claims 1, 2 and 6-20 has been withdrawn.

### ***Claim Rejections - 35 USC § 102***

5. Applicant's arguments, see pages 46-50, filed 10/16/2007, with respect to 35 U.S.C. 102(b) have been fully considered and are persuasive. The rejection of claims 1, 2 and 6-20 has been withdrawn.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 2 and 6-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woodruff *et al.* (*Arthritis & Rheumatism*, **2002**, 46, 2476-85) in view of Fairlie (WO 99/00406) and Kivitz *et al.* (*J. Fam. Prac.*, **2002**, 51, 530-7). Woodruff teach administering an effective amount of the elected species for the treatment of rheumatoid arthritis. Specifically, the compound is a peptidomimetic compound of formula 1 wherein A is NH-acyl, B is the side chain of L-Phenylalanine, C is the side chain of L- Proline, D is the side chain of D-cyclohexylalanine, E is the side chain of L-tryptophan, F is the side chain of L-arginine, and X is  $-(CH_2)_nNH-$ , where n is 3 ((AcF-[OPdChaWR]), abstract left column, paragraph 4, page 2477), satisfying the compound limitations in claims 1, 2, 6-9, 13, 14 and 16-23. Woodruff *et al.* also teach that the cyclic peptide AcF-[OPdChaWR] is a potent antagonist of human and rat C5a receptors on polymorphonuclear leukocytes (PMN's, left column, paragraph 4, page 2477), thus meeting the additional limitation of claim 10. Further Woodruff *et al.* teach a combination therapy of the cyclic peptide with ibuprofen, thus meeting the additional limitation of claim 15. Further, as evidenced by Fairlie, the cyclic analog of AcF-[OpdChaWR] has a C5aR affinity of 0.3  $\mu M$  (Table 6, page 42), thus meeting the additional limitations of claims 11, and 12.

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8. Woodruff *et al.* do not teach that AcF-[OpdChaWR] can be used to treat osteoarthritis. It would have been obvious to one of ordinary skill in the art to administer AcF-[OPdChaWR] to patients suffering from osteoarthritis. The skilled artisan would have been motivated to do so given the teaching of Kivitz *et al.* that pain and inflammation of rheumatoid arthritis and osteoarthritis patients can be treated with the same drugs, NSAIDs. There would have been a reasonable expectation of success given that Woodruff *et al.* teach that AcF-[OPdChaWR] can be used to treat inflammatory conditions (page 2477). Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

#### ***Conclusion***

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Marchetti Bradley whose telephone number is (571)272-9044. The examiner can normally be reached on Monday, Tuesday and Thursday, 8 A.M. to 5:30 P.M.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christina Marchetti Bradley/  
Examiner, Art Unit 1654

/Cecilia Tsang/  
Supervisory Patent Examiner, Art Unit 1654